REMARKS

The pending amendments and the following remarks are submitted as a full and complete response to the Office Action issued on September 26, 2005. Claims 11, 14 and 15 have been amended as explained below. Claim 16 has been added. Support for the new claim can be found, for example, in paragraph [0020] of the specification. No new matter has been introduced by the claim amendments. Claims 1-16 are pending in this Application.

Applicants respectfully request the entry of the claim amendments and favorable reconsideration of the application.

Claim rejections – 35 USC §112, second paragraph

Claim 11 has been rejected as being indefinite as it is unclear what content is referred to in the objected recitation. Claims 14 and 15 have been rejected as being indefinite for missing a unit.

Without acquiescing to the propriety of the examiner's rejection, Applicants have amended claims 11, 14 and 15 to address the examiner's rejection. Claim 11 has been amended to insert the recitation of "layered silicate in the aqueous solution in step (1) is between about 0.5% and about." Applicants note that the recitation was inadvertently deleted from the original claim 11 in the preliminary amendment filed January 24, 2005. Indication of claim 11 as "original" in the preliminary amendment clearly manifests Applicants' intention to maintain the original claim 11. Therefore, the amendment of claim 11 made herein is simply to restore claim 11 to the form as originally filed. Claims 14 and 15 have been amended to recite the unit

as percentage (%). In view of the foregoing amendments, Applicants respectfully request withdrawal of the rejections of claims 11, 14 and 15.

Claim rejections – 35 USC §102(a)

Claims 1, 3 and 4 have been rejected under 35 USC §102(a) as anticipated by Taketoshi et al. ("Taketoshi"). The rejection appears to be based on Taketoshi's disclosure of a blended composition comprising montmorillonite and cyclosporine. See page 3 of the Office Action. Applicants respectfully disagree.

At the outset, Applicants wish to draw the examiner's attention to the amended claim 1 which recites that interlayer cations of the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. Support for the amendment can be found throughout the specification, for example, paragraphs 19 (lines 18-20) and 27 (lines 17-20) of the specification.

Taketoshi fails to teach that interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. In fact, in the composition prepared according to the method disclosed in Taketoshi, the drug with poor water solubility cannot form ionic bonds with the layered silicates.

According to Taketoshi, a drug with poor water solubility is mixed with layered silicates in a mixed solvent of water and a water soluble organic solvent. Under this reaction condition, interlayer cations of the layered silicates are not substituted with hydrogen ions which are necessary for forming ionic bonds between the drug and the layered silicates. As explained in paragraph [0027] of the specification, substitution of

interlayer cations of the layered silicates with hydrogen ions is necessary for the intercalation/adsorption of a drug with no charge such as the drugs recited in claim 1 to produce the claimed hybrid. As a result, one skilled in the art would easily understand that in the composition disclosed in Taketoshi, the drug with poor solubility exists in neutral form (without charge) and is not bound to the layered silicates via ionic bonds. At best, the drug in neutral form (without charge) is bound to the layered silicates via dipolar bonds, if there is any bond.

The way in which the layered silicates are treated in Taketoshi further substantiates that the layered silicates used in Taketoshi to prepare the blended composition are devoid of hydrogen ions. In paragraph [0005] of the English translation of Taketoshi provided by the Examiner, Taketoshi teaches that acid clay can be treated with alkali to be used as layered silicates for the blended composition. Acid clay contains hydrogen ions between the layers. However, during the alkali treatment (for example, with NaOH), hydrogen ions in the acid clay are extracted out of the layers because the hydrogen ions form water with hydroxide under the alkaline environment. As a result, the hydrogen ions are exchanged with cationic ions (for example, Na^+) in the layered silicates. That is, in the layered silicates of Taketoshi, hydrogen ions which are necessary for ionic bonds are replaced with cationic ions.

Since Taketoshi fails to teach or suggest that interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug, it does not qualify as an anticipatory reference. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

Claim rejections – 35 USC §103

Claims 1-15 have been rejected as obvious over Taketoshi. Applicants respectfully disagree.

As explained above in connection with the anticipation rejection, Taketoshi fails to teach or suggest that interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. Especially, Taketoshi lacks the disclosure of the step for substituting interlayer cations with hydrogen ions in the layered silicates.

There is no teaching or suggestion in Taketoshi to motivate one of ordinary skill in the art to modify the disclosed composition or method to produce the claimed hybrid wherein interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. Taketoshi does not even recognize the need for any improvement of the blended composition. Furthermore, Taketoshi fails to provide a reasonable expectation of success for one of ordinary skill in the art to modify the disclosed composition or the disclosed method to produce the claimed hybrid.

Instead, Taketoshi is limited to the blended composition wherein the drug is bound to the layered silicates via dipolar bonds which are much weaker bonds than ionic bonds. In fact, Taketoshi teaches away from the claimed hybrid by teaching a step for removing hydrogen ions which are necessary for ionic bonding from the layered silicates to produce the blended composition. Therefore, Applicants respectfully submit that no *prima facie* case of obviousness exists.

Furthermore, since an ionic bond is much stronger than a dipolar bond in bonding force, the claimed hybrid wherein the layered silicates form ionic bonds with the drug results in an amorphous structure with superior stability in comparison with the blended composition disclosed in Taketoshi.

In view of the forgoing reason, Applicants respectfully submit that neither the claimed hybrid nor the claimed process for preparing the claimed hybrid would have been obvious to one of ordinary skill in the art from the teaching or suggestion of Taketoshi. Therefore, favorable reconsideration and withdrawal of the obviousness rejection are respectfully requested.

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By: G. Franklin Rothwell / Reg. No. 39,627

G. Franklin Rothwell
Registration No. 18,125
Attorney for Applicant
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040

(JOSEPH A. HYNDS
REG. NO. 34,627)

1751-367.AMD1